(c) whether Government have taken any measures to check spreading of the said disease?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (b) No confirmed case of Rocky Mountain spotted fever has been reported in the country.

(c) Does not arise.

Clinical trials of medicines

†2034. SHRI BALAVANT *ALIAS* BAL APTE:
SHRI SHREEGOPAL VYAS:
SHRI VINAY KATIYAR:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Multinational pharma companies carry out clinical trials of their medicines on the patients of our country;

(b) whether it is also a fact that many a times it also adversely affect the patients;

(c) if so, the details thereof;

(d) whether Government are planning to impose ban on multinational pharma companies to carry out such hazardous trials;

(e) if so, the details thereof; and

(f) by when it would be implemented?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) Yes Sir. As per Drugs and Cosmetic Rules Clinical Trials are required to be carried out in the country before applying the marketing permission both by the Indian companies and the MNC pharma companies. Clinical Trial is a key factor to discovery and development of latest modern drugs. MNC pharma companies also carry out global clinical trials in which many countries participate and permission to carry out such trials is given as per Drugs and Cosmetic Rules. Schedule 'Y' of Drugs and Cosmetic Rules, 1945 related to clinical trials have been upgraded and Good Clinical Practice introduced to bring in the contemporary global standards.

†Original notice of the question was received in Hindi.

(b) and (c) All Drugs have side effects depending upon their mechanism of action. Permission to conduct the clinical trial is given after reviewing the risk versus benefit aspects. The permission to conduct the trial is given in phases. Phase I is the trial when the drug is administered first time to the humans and in this phase mainly adverse effect of the drug is monitored and maximum tolerated dose is calculated. As per Drugs and Cosmetic Rules, the Phase I on molecules discovered outside the country is not permitted only repeat Phase I is permitted.

Permission to carry out Phase II, III and IV of the clinical trial is given only after scrutinizing the data of the earlier phases.

Apart from the regulatory approval of the ethics committees of the respective hospitals approve these trials. The reports of adverse events if any are submitted both to the ethics committees and regulatory authorities within 14 days. The subjects in the trial are enrolled in these trials only after their written informed consent which has an option to opt out of the trial without giving any reason. The regulatory authorities can terminate the trial at any time on the ground of any safety issues. The regulatory inspections of the clinical trials are also being initiated.

(d) No, Sir. Clinical Trials are being permitted in accordance with relevant provisions of Drug & Cosmetics Rules, 1940

(e) and (f) Do not arise.

Organ trade

†2035. SHRI BALAVANT *ALIAS* BAL APTE:
SHRI SHREEGOPAL VYAS:
SHRI VINAY KATIYAR:
SHRIMATI VIPLOVE THAKUR:
SHRI PYARELAL KHANDELWAL:
SHRI JAI PRAKASH AGGARWAL:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the fact that the illegal trade of human organs is going on a large scale in the country especially in Delhi and the cities falling under the National Capital Region, Delhi;

†Original notice of the question was received in Hindi.